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ARAB CODEX INITIATIVE
المبادرة العربية للدستور الغذائي

A.I.D.S.M.O

27th Meeting of the Codex Contact Points in the Arab Region

ANALYSIS OF AGENDA ITEMS IN PREPARATION FOR THE 27th SESSION OF THE CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOOD (CCRVDF27)

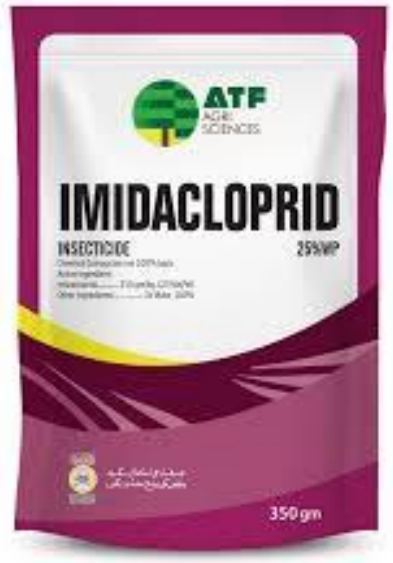
27TH SESSION OF THE CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

CCRVDF

Agenda item 6

Item 6

MRLs for veterinary drugs in foods arising from JECFA98 (2024)



CCRVDF27 (2024)

MRLs for veterinary drugs in foods arising from JECFA98 (2024)

98th Meeting of JECFA (2024)

- **JECFA evaluated the safety of two veterinary drugs:**

Clopidol and fumagillin dicyclohexylamine

- **JECFA completed the safety evaluation of:**

imidacloprid

Although ethoxyquin was on the review list, it was not evaluated due to a lack of data from the sponsor.

Toxicological monographs summarizing the data considered by JECFA98 in establishing ADIs is published in the WHO Food Additives Series No. 89. Residue monographs summarizing the data considered by JECFA98 in recommending MRLs is published in FAO JECFA Monographs No. 33. The summary report of JECFA98 is available on the FAO and WHO webpages for consultation.

The meeting report is published in the WHO Technical Report Series (TRS 1055).

CCRVDF27 (2024)

CLOPIDOL

Key Points

Classification: Clopidol is a coccidiostat used primarily in veterinary medicine to prevent and control coccidiosis in poultry and other food-producing animals.

Mechanism of Action: It works by inhibiting the growth and reproduction of coccidia, parasites that can cause severe intestinal disease in affected animals.

Safety Evaluations: Clopidol has not previously been evaluated by JECFA. The Committee evaluated clopidol at the request of the CCRVDF at its twenty-sixth Session in order to establish relevant health-based guidance values and to recommend MRLs for residues in chicken liver, kidney, muscle and skin/fat.

MRLs Proposition

Specie	Tissue	MRLs (µg/kg) recommended by JECFA98	For consideration by CCRVDF27 at Step
Chicken	Kidney	8800	4
Chicken	Liver	10400	4
Chicken	Muscle	4100	4
Chicken	Skin/Fat	2600	4

Agenda item 6

CCRVDF27 (2024)

Fumagillin dicyclohexylamine

Key Points

Usage: Commonly used in the treatment of Nosema disease in bees and for certain parasitic infections in fish. Its application helps to maintain animal health and improve production efficiency.

Safety and Efficacy: The Committee evaluated fumagillin DCH at the present meeting at the request of the CCRVDF at its Twenty-sixth Session with a view to establishing relevant health-based guidance values and recommending MRLs for fish and for honey.

The Committee noted that a suitable analytical method for the determination of DCH in fish fillet should be developed.

MRLs Proposition

Species	Tissue	MRLs (µg/kg) recommended by JECFA98	For consideration by CCRVDF27 at Step	Notes
Fish	Fillet	10 (For the marker residue (MR) fumagillin)	4	Residues of DCH (including any potential metabolites) should be monitored when fumagillin DCH preparations are used in fish to ensure that the concentration is < 1000 µg/kg, a target level compatible with the upper bound of the ADI. A suitable analytical method for the determination of DCH in fish fillets would need to be developed (JECFA98, 2024)
-	Honey	20 (For the marker residue (MR) DCH)	4	

CCRVDF27 (2024)

Imidacloprid (neonicotinoid parasiticide)

Key Points

Uses: It is commonly used in crop protection, as well as in veterinary medicine. It is also employed in termite control and as a flea treatment in dogs and cats. It is used to control sea lice on farmed fish and to control sucking insects, chewing insects (including termites), soil insects and fleas on pets. Imidacloprid may be applied to structures, crops and soil and can be used as seed treatment.

Safety Evaluations: Imidacloprid was first evaluated by JMPR in 2002**,** The 98th meeting included imidacloprid on the agenda to complete its assessment, particularly regarding microbiological data submitted by the sponsor.

Environmental Impact: The persistence of imidacloprid in the environment and its potential to contaminate.

MRLs Proposition

Species	Tissue	MRLs (µg/kg) recommended by JECFA98	For consideration by CCRVDF27 at Step	Notes
Atlantic salmon and rainbow trout	Fillet (muscle with skin in natural proportions) and/or muscle	600	4	The MRL should be extrapolated to all fin fish (JECFA98, 2024).

General Comment and recommandation for Arab region

Arab countries should consider the adoption of JECFA's recommendations and guidelines for compounds clopidol, fumagillin dicyclohexylamine and also imidacloprid, which is essential for ensuring food safety and protecting public health in Arab countries.

These guidelines, which include acceptable daily intakes (ADIs) and maximum residue limits (MRLs), provide a scientifically based framework for assessing the safety of veterinary drug residues in food products.

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Arab countries should pay particular attention to aligning their regulatory standards with the international best practices, to safeguard both animal and human health. However, national adoption will need to consider local uses and regulatory measures, agricultural practices, and specific public health concerns, requiring a thorough review and possible adaptation of JECFA's recommendations to suit the regional context.

Agenda item 7: MRL extrapolation for veterinary drugs

Item 7

Extrapolation of MRLs for veterinary drugs in foods to one or more species

Item 7.1	Extrapolated MRLs for different combinations of compounds/commodities at Step 4
Item 7.2	Other matters related to the extrapolation of MRLs for veterinary drugs in foods to one or more species

Agenda item 7

CCRVDF26 (2023)

- Agenda item 7.1: Extrapolated MRLs for different combinations of compounds/commodities at Step 4
  Agenda Item 7.2: Other matters related to the extrapolation of MRLs for veterinary drugs in foods to one or more species

Adoption of the MRL extrapolation approach in several sessions of CCRVDF

Make the MRLs of veterinary drug residues more available
Overcome the lack of scientific data needed for risk assessment

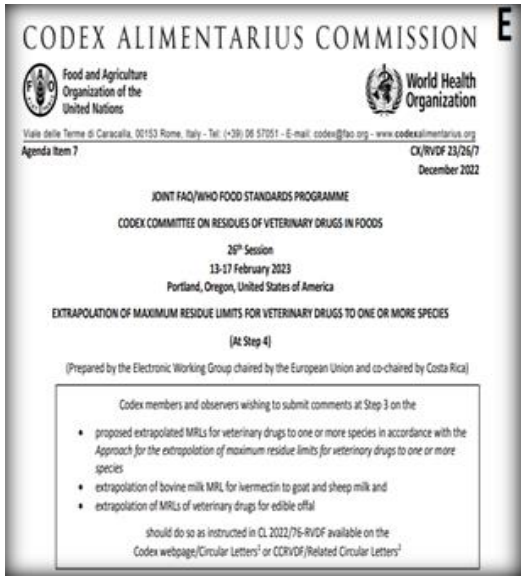
CCRVDF24

Establishment of an EWG

Develop a pragmatic approaches to extrapolate MRLs to one or more species

Compare these approaches with the revised Option C for aquatic species

Conduct a pilot study on the extrapolation of some compounds



CODEX ALIMENTARIUS COMMISSION

E

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 7

CX/RVDF 23/26/7

December 2022

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

26th Session

13-17 February 2023

Portland, Oregon, United States of America

EXTRAPOLATION OF MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS TO ONE OR MORE SPECIES

(At Step 4)

(Prepared by the Electronic Working Group chaired by the European Union and co-chaired by Costa Rica)

Codex members and observers wishing to submit comments at Step 3 on the

- proposed extrapolated MRLs for veterinary drugs to one or more species in accordance with the *Approach for the extrapolation of maximum residue limits for veterinary drugs to one or more species*
- extrapolation of bovine milk MRL for ivermectin to goat and sheep milk and
- extrapolation of MRLs of veterinary drugs for edible offal

should do so as instructed in CL 2022/76-RVDF available on the Codex webpage/Circular Letters[1] or CCRVDF/Related Circular Letters[2]

Establishment of principles/practical modalities of application

Extension of the approach to all animal species (beyond aquatic species)

Modification of the Risk Analysis Principles applied by the CCRVDF to provide more autonomy to risk managers to propose extrapolation of MRLs to one or more species

Agenda item 7

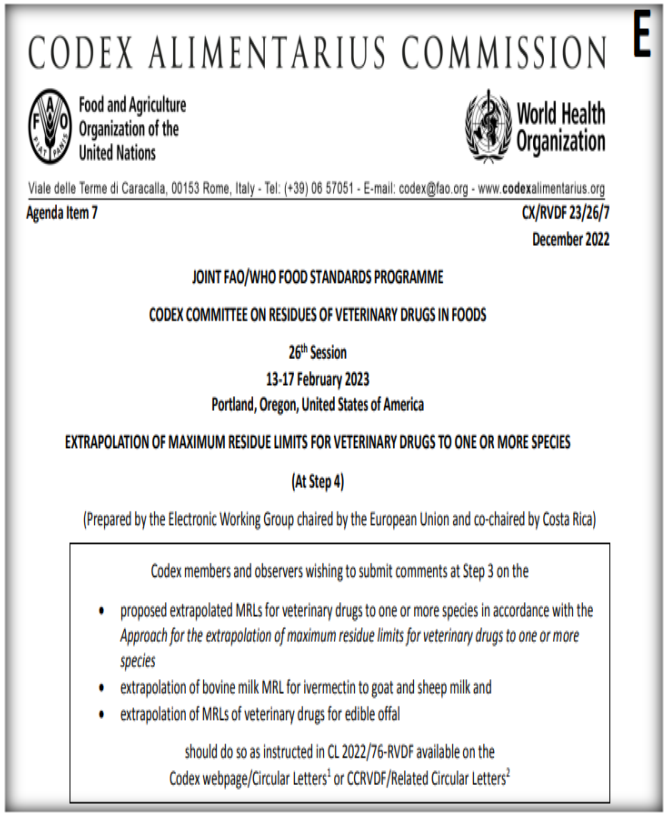
CCRVDF26

Discussion of the EWG's proposals

Used the agreed rules to extrapolate MRLs for several substances which were adopted by CAC46 (2023)

agreed that the extrapolation EWG should consider approaches to extrapolate MRLs for certain veterinary drugs to camelids.

agreed to establish an electronic working group (EWG to further work on the extrapolation of MRLs notably for edible tissues and for milk .



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Agenda Item 7 — CX/RVDF 23/26/7

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CCRVDF25

Adoption by CAC44 (2021) and its inclusion as Annex C of the Risk Analysis Principles

Establishment of an EWG

Prepare revised proposals for consideration by the Twenty-sixth Session of the CCRVDF

Consider the extrapolation of MRLs for Ivermectin in milk from goats and sheep

Develop an adapted approach for offal tissues

CCRVDF26

EWG: Termes of reference

The EWG was charged with working on the following topics:

- **Lufenuron**
- **Emamectin benzoate**
- **Diflubenzuron**

- ❑ Continue to evaluate the extrapolation of MRLs for different combinations of compounds/commodities, particularly for considering the extrapolation of MRLs in finfish for:

- ❑ Summarize available information on the distribution of compounds in different edible offal tissues with a view to evaluating the possibility of extrapolating MRLs to edible offal tissues other than liver and kidney.

- ❑ Examine opportunities to enhance the current criteria's potential for extrapolation across species where justified, such as between ruminants and camels and between milk of different species.

CCRVDF27

EWG RECOMMENDATION ABOUT THE APPLICATION OF MRL EXTRAPOLATION APPROACH

EXTRAPOLATING MRLS FOR LUFENURON, EMAMECTIN BENZOATE, AND DIFLUBENZURON TO FINFISH

Lufenuron:

The EWG agreed that the extrapolation criteria are met for lufenuron and that extrapolation to finfish can be recommended.

Emamectin benzoate:

Criterion 2b of the established extrapolation rules states that the marker residue in the reference species should be the parent compound only

or the total residues of toxicological concern.

With the proposed amendment, emamectin benzoate to finfish could be recommended.

Diflubenzuron

agreed that the extrapolation criteria are not met for diflubenzuron. In

Amendment of Criterion 2b of the Approach for the extrapolation

CCRVDF27 EWG RECOMMENDATION ABOUT THE APPLICATION OF MRL EXTRAPOLATION APPROACH

EXTRAPOLATING MRLS FOR LUFENURON, EMAMECTIN BENZOATE, AND DIFLUBENZURON TO FINFISH

2 The MRL of 1350 µg/kg established for lufenuron in salmon and trout fillets can be extrapolated to finfish.

3 With agreement on R1, the MRL of 100 µg/kg established for emamectin benzoate in muscle and fillet of salmon and trout can be extrapolated to finfish.

4 Extrapolation of the MRL established for diflubenzuron in the muscle of salmon is not supported.

Agenda item 7

CCRVDF27

RECOMMENDATION 2: DEVELOPMENT OF A POSSIBLE APPROACH FOR EXTRAPOLATION OF MRLS TO CAMELIDS:

Extrapolation of MRLs can be supported where the following criteria are satisfied:

1. *Extrapolation* ***should only occur between the same tissues/food commodities in the reference and concerned species***
2. ***The marker residue is the parent compound****.*
   a. In cases where the active substance is a combination of homologous compounds, the marker residue can be considered the same as the parent if it is a homolog that is a major component of the active substance.
3. ***For meat tissues, extrapolation of reference species MRLs to camelids on a one-to-one basis should be considered***

- *if either:*
- *a. identical MRLs have been established in at least one ruminant species and one non-ruminant mammalian species based on JECFA recommendations, and the M:T ratio used by JECFA was 1 in all tissues for the ruminant and nonruminant species, OR*
- *b. Based on JECFA recommendations, identical MRLs have been established in at least one ruminant, non-ruminant mammalian, and avian species. JECFA used the same M:T ratio for each tissue type for all three species.*

4. *Where conditions 2 and 3 are satisfied, extrapolation of an MRL for milk should also be considered in those cases where the M:T ratio used by JECFA was 1 in milk.*

Agenda item 7

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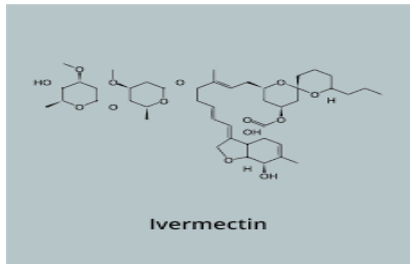
Recommendation 3: Opportunities to enhance the current criteria's potential for extrapolation between the milk of different species, with a particular focus on deltamethrin and ivermectin. Proposed EWG recommendation for ivermectin



Ivermectin and deltamethrin

Extrapolation of the cattle milk MRL for ivermectin and deltamethrin to the milk of other ruminants are not recommended.

Criterion 2b of the Approach should be amended to:

"The marker residue in the reference species is the parent compound only or is the same as the total residues of toxicological concern, or the Codex MRL status in the reference species is 'unnecessary', and there is an expectation that the active substance will be used under the same conditions (i.e., by the same administration routes and at similar doses) in both species.

i. In cases where the active substance is a combination of homologous compounds, the marker residue can be considered the same as the parent if it is a homolog that is a major component of the active substance."

Except for Recommendation R1 above, the current criteria for extrapolating between milk of different species are not enhanced.

Agenda item 7

Recommendation 4: Development of a possible approach for extrapolation of MRLs to edible offal tissues other than liver and kidney

The EWG was unable to develop a suitable approach to extrapolate MRLs for veterinary drug residues in edible offal tissue

1. determine if further work would be needed in this regard and if so
2. guide any future EWG on the task it is charged with.

3. For substances with an MRL classification of "unnecessary" or "not specified" in standard tissues, could the same classification be extrapolated to non-standard offal tissues without further consideration?

CCRVDF has already concluded that, for these substances, residues in the diet do not represent a consumer safety concern. What is the difference between the terms "unnecessary" and "not specified"?

Fundamental questions remain on which it would be useful to have input from CCRVDF

To address the issues identified by the EWG, CCRVDF is invited to provide further guidance regarding Recommendation 4 to allow additional work in an EWG if appropriate.

General Comment and recommendations for Arab region

It would be appropriate to support the adoption of the proposed standards developed by the extrapolation approach Lufenuron and Emamectin benzoate at step 5/8 given the importance of establishing MRLs, especially for Arab countries for which Codex is considered as the reference for food standards.

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It would be appropriate to support EWG recommendations to continue the discussion on the MRL extrapolation approach for edible tissues given the limitations and concerns identified by the EWG.

To address the absence of MRLs for camel products, it is recommended that Arab delegates encourage the adoption of the proposed extrapolation criteria and advocate for the inclusion of MRLs for camels in the CCRVDF priority lists. Additionally, it is important to encourage generation of data supporting the establishment of MRLs for camelid tissues alongside other species.

AGENDA ITEM 8.1

Criteria and Procedures for the Establishment of Action Levels for Veterinary Drugs in Food of Animal Origin Resulting from Unavoidable and Unintentional Veterinary Drug Carry-Over in Non-Target Animal Feed

Agenda Item 8.1

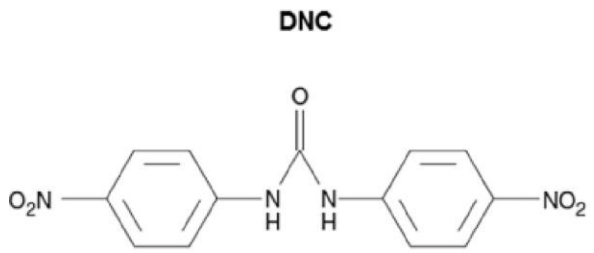
Prepared by the EWG

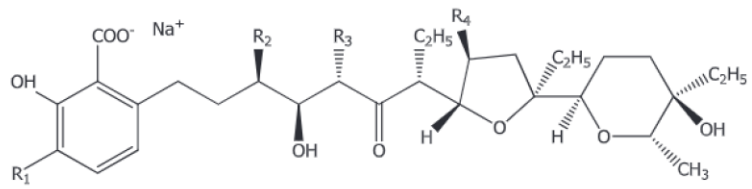
Chaired by Australia and co-chaired by Canada

TOR

- Develop the criteria and procedures for establishing **action levels.**

- Revisit the **Nicarbazin and Lasalocid** carry-over in chicken eggs as pilot studies in support of the suggested procedure.





APPENDIX I
Proposed Approach

Action Levels for Veterinary Drug Residues in Food Products from Non-Target Animals

Linked to the Unintended and Unavoidable Veterinary Drug Carry-Over in Non-Target Animal Feed

- Action levels should be based on the '**As Low as Reasonably Achievable**' concept and only be derived where the framework of the CoP on Good Animal Feeding, GMPs, and/or HACCP has been used to minimize the veterinary drug carry-over.

- Action levels should be developed only to cover situations where low-level residues of an approved/registered veterinary drug used according to good veterinary practices are consistently detected by a competent authority in edible commodities from non-target animals and investigations confirm the source to be unintended and unavoidable carry-over.

- Action levels for non-target animals should be derived only for veterinary drugs **authorized for use** in a target class of animals and have MRLs.

- **Analytical methods** should be available for the veterinary drug residue in the **edible commodity**.

APPENDIX I
Proposed Approach for Establishing Action Levels

PROCEDURE

CCRVDF

- Step 1. Assess animal dietary exposure
- Step 2. Estimate anticipated residue levels in food commodities of animal origin
- Step 3. Set Action levels

JECFA

- Step 4. Evaluate human dietary exposure assessment

APPENDIX II

PILOT STUDY A:
Estimating Action Levels for Unavoidable and Unintentional **Nicarbazin** Carry-Over in Chicken Egg

PILOT STUDY B:
Estimating Action Levels for Unavoidable and Unintentional **Lasalocid** Carry-Over in Chicken Egg

- Target animals: chicken (broilers)
- Non-target animals: Laying hens
- Reason of carry-over: feed for chickens and laying hens is often prepared at the same feed mill
- Data: survey or residue monitoring data in poultry eggs
- **Nicarbazin**: proposed action level: 0.22 mg/kg
- **Lasalocid**: proposed action level: 0.1 mg/kg

Agenda Item 8.1

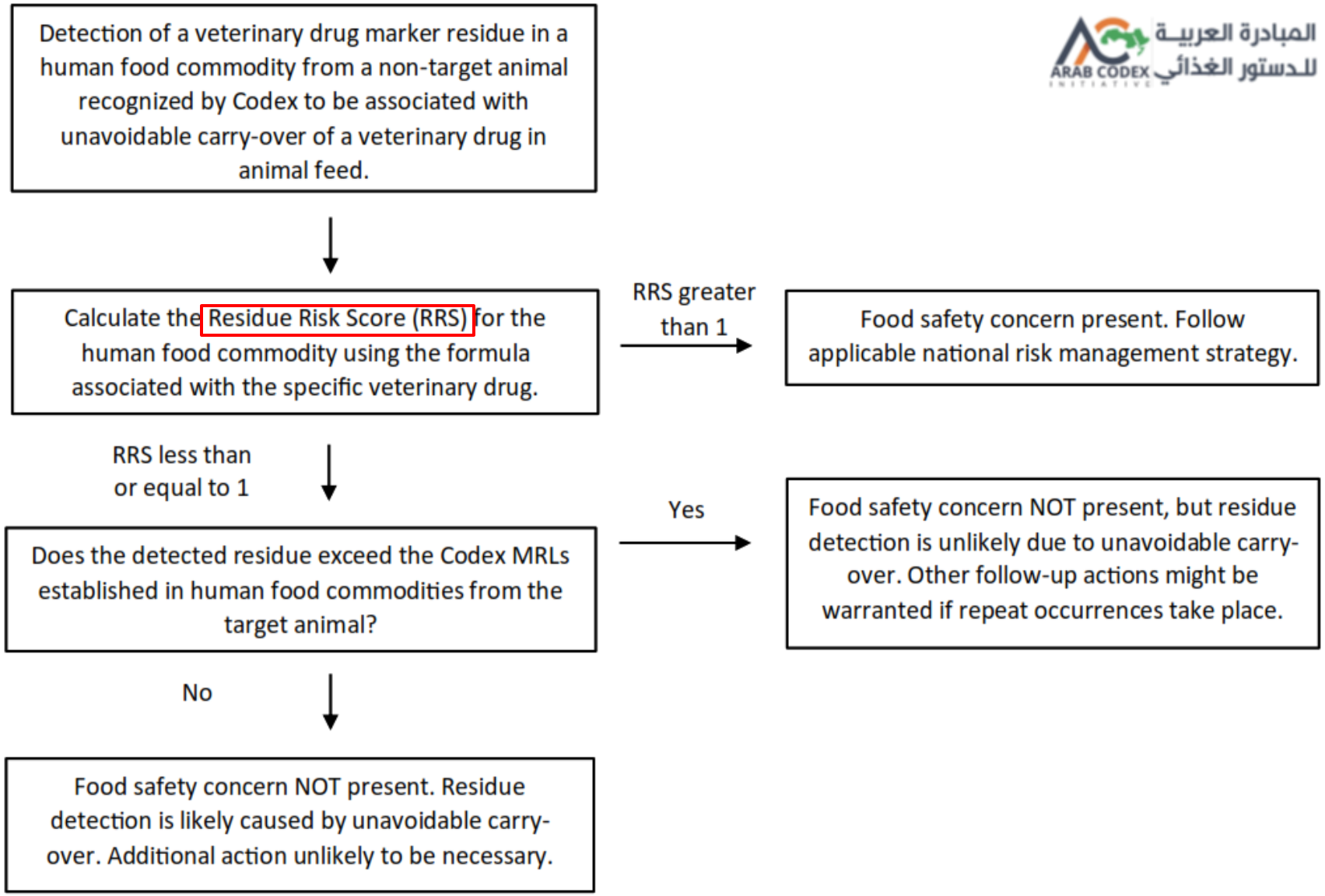
Alternative Approach from the United States of America (USA)

APPENDIX III

Proposal to Develop Carry-Over Risk Management Information Based on a Risk Management Decision Tool

APPENDIX III

Alternative Approach Based on a Risk Management Decision Tool (RMDT)



CCRVDF

CCRVDF27 is invited to consider the recommendations below:

- The proposed approach to establishing action levels as presented in **Appendix I** (for comments).
- Pilot studies using nicarbazin and lasalocid residues in chicken eggs to illustrate the proposed approach (**Appendix II**).
- The alternative approach submitted by the United States of America as presented in **Appendix III** (for comments).

Should Codex members support the approach proposed by the EWG in Appendix I, consider whether the action levels proposed for nicarbazin and lasalocid in eggs in Appendix II, could be submitted for adoption by CAC47.

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The development of systematic, data-driven methodologies to address the longstanding issue of unintended veterinary drug carryover, including pilot studies and their outcomes, is highly commendable.

However, **Arab delegations may consider** supporting a more straightforward and practical risk management approach. This would help overcome:

- challenges related to data availability
- avoid barriers to trade due to setting very low action levels
- and make the solution more accessible to countries with varying levels of development.


thank you
danke
謝謝
ngiyabonga
рахмат
teşekkür ederim
Баярлалаа
спасибо
faafetai lava
vinaka
спасибі
blagodaram
dank je
misaotra
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